UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
***Johns v. CR Bard et al.*,**
Case No. 2:18-cv-1509

EVIDENTIARY MOTIONS OPINION AND ORDER NO. 9

This Opinion addresses the parties' motions to exclude or limit the testimony of regulatory experts. This includes Defendants' Motion to Exclude the Opinions and Testimony of Plaintiff's Expert John L. Quick (ECF No. 32), Plaintiff's Motion to Exclude the Opinions and Testimony of Defense Expert Donna-Bea Tillman, Ph.D. (ECF No. 113), Plaintiff's Motion to Exclude the Opinions and Testimony of Defendants Bard's Expert Witness Kimberly A. Trautman, M.S. (ECF No. 72), Plaintiff's Motion to Exclude the Opinions and Testimony of Defense Expert Marion J. Fedoruk, M.D. (ECF No. 43), Plaintiff's Motion to Exclude the Opinions and Testimony of Defense Expert Greg Richey (ECF No. 97), and Plaintiff's Motion to Exclude the Opinions and Testimony of Defense Expert Thomas Michael Galassi, MPH, CIH (ECF No. 138).

I. Background[1]

This case is the first bellwether trial, selected from thousands of cases in this multidistrict litigation, alleging "that defects in defendants' polypropylene hernia mesh

[1] The Court assumes that the parties and other interested readers are familiar with the history of this case. For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order. *In re Davol, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1–6 (S. D. Ohio Sept. 1, 2020).

products can lead to complications when implanted in patients, including adhesions." *In re Davol, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1 (S. D. Ohio Sept. 1, 2020). This includes the Ventralight ST, the device implanted in Plaintiff. The Ventralight ST is a prescription medical device used for hernia repairs. The Food and Drug Administration ("FDA") cleared it for use through the premarket notification 510(k) process in 2010 and later cleared it for use with the Echo Positioning System in 2011. It is a multicomponent device made of a mesh, which consists of polypropylene, polyglycolic acid fibers, and a bioresorbable coating called "Sepra Technology" ("ST"). The ST-coated side of the mesh is placed against organs, such as the bowels, while the uncoated polypropylene side is placed against the fascia because the uncoated side maximizes tissue attachment and thus supports the hernia repair. *Id.* at *1–2.

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Defendants' allegedly defective Ventralight ST device. Plaintiff claims that Defendants knew that polypropylene is unsuitable for permanent implantation in the human body. *Id.* at *4. The crux of Plaintiff's claims is that the ST coating on Ventralight ST devices resorbs too quickly. *Id.* at *1. This leads to the exposure of bare polypropylene to internal organs and tissues, increasing the risk of potential complications. *Id.* at *1–3. Plaintiff alleges that this occurrence led to omental adhesions after his laparoscopic hernia repair surgery in 2015. *Id.* at *4. The following claims remain for trial: design defect, under negligence and strict liability theories; failure to warn, under negligence and strict liability theories; breach of express warranty; breach of implied warranty; breach of implied warranty of merchantability; negligent

misrepresentation; and punitive damages. *Id.* at *6–25. Now, various evidentiary motions are ripe for adjudication.

II. Legal Standard

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975) ("A better practice is to deal with questions of admissibility of evidence as they arise."). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (quoting *Ind. Ins. Co.*, 326 F. Supp. 2d at 846). The denial, in whole or in part, of a motion in limine does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

The burden is on the party offering the expert testimony to demonstrate by a preponderance

of proof that the opinions of their experts are admissible. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). Any doubts regarding the admissibility of an expert's testimony should be resolved in favor of admissibility. *See Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) ("The Court [in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993),] explained that Rule 702 displays a 'liberal thrust' with the 'general approach of relaxing the traditional barriers to "opinion" testimony.'" (quoting *Daubert*, 509 U.S. at 588)); Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("A review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.").

III. Analysis

> Expert testimony is admissible if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. In this circuit, "[t]he Rule 702 analysis proceeds in three stages." *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2016). "First, the witness must be qualified by 'knowledge, skill, experience, training, or education.' Second, the testimony must be relevant, meaning that it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' Third, the testimony must be reliable." *Id.* (quoting *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008)).

First, an expert witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "[T]he issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation

for a witness to answer a specific question." *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). "[T]he only thing a court should be concerned with in determining the qualifications of an expert is whether the expert's knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth. The weight of the expert's testimony must be for the trier of fact." *Mannino v. Int'l Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981). A party's expert need only meet the "'minimal qualifications' requirement—not one who could teach a graduate seminar on the subject." *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014) (quoting *Mannino*, 650 F.2d at 851); *see also Dilts v. United Grp. Servs., LLC*, 500 F. App'x 440, 446 (6th Cir. 2012) ("An expert's lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact.").

Second, expert testimony must also be relevant, meaning it will "help the trier of fact to understand the evidence or to determine a fact in issue." *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 208 (6th Cir. 2015) (quoting *United States v. Freeman*, 730 F.3d 590, 599–600 (6th Cir. 2013)); *see also* Fed. R. Evid. 702(a). "Expert testimony which does not relate to any issue in the case is not relevant, and, ergo, non-helpful." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993) (quoting 3 J. Weinstein & M. Berger, Weinstein's Evidence ¶ 702[02], p. 702–18 (1988)). "This requirement has been interpreted to mean that scientific testimony must 'fit' the facts of the case, that is, there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify." *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 592). This is a case-specific inquiry. *Madej*, 951 F.3d at 370 ("Whether an opinion 'relates to an issue in the case' or helps a jury answer a 'specific question' depends on the claims before the court.").

Finally, expert testimony must also be reliable. Rule 702 provides the following general standards to assess reliability: whether "the testimony is based on sufficient facts or data," whether "the testimony is the product of reliable principles and methods," and whether "the expert has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702(b)–(d). To evaluate reliability of principles and methods, courts consider "'testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community,'" though these factors "'are not dispositive in every case' and should be applied only 'where they are reasonable measures of the reliability of expert testimony.'" *In re Scrap Metal*, 527 F.3d at 529 (citations omitted); *see Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) (describing these factors as "flexible" (quoting *Daubert*, 509 U.S. at 594)). The objective of the reliability requirement is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152.

The parties challenge the opinions and testimony of John L. Quick, Dr. Donna-Bea Tillman, Ph.D., Kimberly A. Trautman, Dr. Marion J. Fedoruk, M.D., and Greg Richey—all of whom offer a regulatory opinion or one related to Material Safety Data Sheets ("MSDSs").

A. John Quick

Plaintiff offers an expert report and testimony from Quick considering the adequacy of Defendants' Quality Management System ("QMS") "during the relevant phases of numerous medical device design and development processes." (ECF No. 63 at PageID #3007.) Defendants contend that Quick is unqualified to offer this testimony, that his opinions are irrelevant because they lack a connection to the Ventralight ST, and his methods are unreliable. (ECF No. 32 at

PageID #1108–09.) Although Quick is qualified to opine on the adequacy of Defendants' QMS and his opinions regarding the adequacy of Defendants' QMS in relation to the validation of the Sepra Technology ("ST") are relevant, Quick's opinions are unreliable and thus inadmissible.

As a preliminary matter, most of Quick's opinions in his report are inadmissible due to earlier opinions addressing motions in limine. Quick's opinions address the QMS in place for the Composix Kugel XL device and other devices, as well as the status of Defendants' QMS prior to the development of the Ventralight ST, its components, or a predicate device. (ECF No. 32-2 at PageID #1171, 1182.) As this Court has held before, this is inadmissible character evidence because it is being used to show that earlier inadequacies in the QMS show inadequacies in the QMS in place at the time the Ventralight ST was designed and manufactured. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, 2:18-cv-1509, 2021 WL 81821, at *6 (S.D. Ohio Jan. 11, 2021); Fed. R. Evid. 404(a); *see also In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, 2:18-cv-01509, 2020 WL 6440261, at *6–7 (S.D. Ohio Nov. 2, 2020) (reaching the same conclusion for evidence of other regulatory noncompliance ices). For these reasons, Quick's opinions about the adequacy of the QMS in place for other devices and prior to the development of the Ventralight ST cannot be offered to prove that the QMS in place for the Ventralight ST was defective.[2]

The only portion of Quick's report that addresses the Ventralight ST is his final section, in which he opines that "the user need of the 14-day resorption time for the Sepra Technology was

[2] Quick also opined that Genzyme, the company from which the Defendants purchased the license for the ST, needed to file a new 510(k) application and that the failure to do so was evidence that Defendants had made little progress on these QMS issues since 2006. (ECF No. 32-2 at PageID #1206–07.) This is also inadmissible character evidence introduced to demonstrate propensity. For this reason, the Court need not decide whether Quick is also qualified to offer this opinion. (*See* ECF No. 89 at PageID #6072 (raising the issue).)

never validated by either Genzyme or Bard in the Sepramesh products or the Ventralight ST products." (ECF No. 32-2 at PageID #1202.) Consequently, the only remaining opinions that Defendants challenge in their motion are that "Bard failed to validate the Hydrogel Technology used in the Ventralight ST hernia device" and other testimony implicated in that section of the report on the following subjects: "[hernia] mesh," "[a]nimal studies with regard to mesh products," "[b]iocompatibility testing," and "[e]valuating or determining which tests should be conducted during the design and development process of a hernia mesh product." (ECF No. 32 at PageID #1106–07.)[3] Thus, Defendants' arguments are addressed in relation to these opinions.

First, qualifications. Quick is qualified through his experience to offer opinions on the adequacy of Defendants' QMS in place during the design and manufacture of the Ventralight ST and/or its components. Quick was responsible for "large medical device and drug related product functions," at Baxter International, Inc., focusing on sterile fluids technology and medical devices and having all medical device operations certified based on standards from the International Organization for Standardization ("ISO"). (*Id.* at PageID #1162.) He eventually served as the "Corporate Vice President for Worldwide Quality/Regulatory." (*Id*. at PageID #1162–63.) Since 2003, Quick has worked as a private consultant on quality management and regulatory compliance "with a special emphasis in medical device quality system matters." (*Id.* at PageID #1163.) He advises medical device companies on how they can improve their quality systems and reporting to the FDA, how to respond to FDA warning letters, and how to prepare for FDA QMS inspections. (*Id.*) Additionally, Quick assists private equity firms with due diligence on pharmaceutical and medical device companies, evaluating their quality assurance, quality control, regulatory compliance and affairs, and manufacturing and research and development. (*Id.*) This is sufficient

[3] Defendants list other areas of testimony as inadmissible, but because Plaintiff admits that Quick does not opine on those areas (ECF No. 63 at PageID #3021–23) there is no occasion to address them.

to show that Mr. Quick is qualified to opine from a QMS perspective whether Defendants properly validated the Sepra Technology, as well as each of the opinions that Defendants challenge.

Defendants argue that Quick is unqualified to offer any of these opinions because he is not a medical doctor or chemist (ECF No. 32 at PageID #1113–14), but this is unpersuasive. "[I]nsistence on a certain kind of degree or background is 'at odds with the "liberal thrust" of the Federal Rules and their "general approach of relaxing the traditional barriers to 'opinion' testimony."' 'The language of Rule 702 and the accompanying advisory committee notes make clear that various kinds of "knowledge, skill, experience, training, or education," qualify an expert as such.'" *In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712, 731 (N.D. Ohio 2011) (citations omitted). Here, Quick is qualified by way of his experience.

Additionally, Defendants assert that Quick is not a hernia mesh expert (ECF No. 32 at PageID #1113–14), but the Court can discern no reason why QMS expertise must be device specific. FDA regulations define a "quality system" as "the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management." 21 C.F.R. § 820.3(v). These requirements, known as the "[c]urrent good manufacturing practice," "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." *Id.* at § 820.1(a)(1). These are not device-specific systems. ISO standards are also not device-specific. *See* ISO 13485, Medical Devices, *ISO*, https://www.iso.org/iso-13485-medical-devices.html (last visited May 5, 2021). In other words, the principles of QMS appear to be broadly applicable across various types of medical devices.

Next, relevance. Quick's remaining opinions are relevant to the extent that he argues Defendants failed to have an adequate QMS in place for validation of the ST coating component

of the Ventralight ST. As this Court has explained before, ISO standards are relevant to the duty of care that Defendants owed Plaintiff. *In re Davol, Inc./C.R. Bard, Inc.*, *Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6603657, at *7 (S.D. Ohio Oct. 20, 2020) (citing *Downing v. Hyland Pharmacy*, 194 P.3d 944, 948 (Utah 2008)). Defendants argue that Quick "did not attempt to connect his review of the design process for any Bard device to *any* of the alleged injuries in this case" and that no connection exists in the record. (ECF No. 32 at PageID #1112; ECF No. 89 at PageID #6070–72.) But at the summary judgment stage, the Court concluded that there was a genuine issue of fact whether an alternative design, including "different formulations of the resorbable coating that is alleged to be defective here" would have prevented Plaintiff's injury. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 5223363, at *12 (discussing Dr. Babensee's opinions). For this reason, Plaintiff's design defect claim survived summary judgment. *Id.* Thus, Quick's opinions are relevant to this case.

Finally, reliability. Quick's method appears to be reliable. At the beginning of his report, Quick outlines the need under ISO 13485 to establish "user needs" and to "validate" those needs throughout the design process. (ECF No. 32-2 at PageID #1167.) Then, he relies on this principle from ISO 13485 to explain why Defendants should have validated the pertinent user need for ST coating—a fourteen-day resorption period—and how they did not successfully do so. (*Id.* at PageID #1202–05.) Specifically, Quick points out various communications where officials at Bard or Davol acknowledged the fourteen-day claim and ultimately concludes that "[n]one of the testing on the Design Verification appear related to or otherwise validate that the end user need of a 14 days resorption window is met." (*Id.* at PageID #1205.)[4]

[4] Defendants contend that Quick is "a quintessential 'expert-for-hire.'" (ECF No. 32 at PageID #1116.) But this is not the problem with Quick's testimony. When "a proposed expert's testimony flows naturally from his own current or prior research (or field work), then it may be appropriate for trial judge" to admit the testimony, which is "in line with the notion that an expert who testifies based on research he has conducted independent of litigation

However, Quick's application of the method is unreliable because he did not review all the pertinent materials that would indicate whether the Defendants had properly validated the 14-day user need for the ST coating. FDA regulations require that design files or design history files for a medical device include design validation, meaning that "the devices conform to defined user needs." 21 C.F.R. § 820.30. This appears to be identical to basic principles of ISO 13485. However, Quick admitted that he had not reviewed the entirety of the design files for the Ventralight ST because the documents were "not very well organized." (ECF No. 32-1 at PageID #1144, p. 137.) Quick explained that he typically would review the entire design file but did not here. *Id.* Thus, it is a significant reliability issue that Quick did not review the whole Ventralight ST design file to form opinion that the 14-day resorption window user need for the ST coating w was not validated. Quick also could not confirm that he had reviewed all animal studies. (ECF No. 32-1 at PageID #1144, p. 138.) This is critical because he opined that Defendants failed to validate the ST coating while considering one animal study that did not address the fourteen-day resorption window. (ECF No. 32-2 at PageID #1205–06.) This user-need validation opinion becomes markedly less reliable when the expert has not reviewed all the relevant materials related to the validation of the user needs of Ventralight ST. For these reasons, opinion is unreliable.

In response, Plaintiff offers no arguments other than Defendants' expert also did not review "every document relating to the products at issue." (ECF No. 63 at PageID #3020.) But this is deficient. It is Plaintiff's burden to demonstrate that his expert's testimony is admissible, which he fails to do here. Plaintiff does not explain why the documents Quick *did* review were sufficient

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'provides important, objective proof that the research comports with the dictates of good science.'" *Johnson v Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 435 (6th Cir. 2007) (quoting *Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1317 (9th Cir. 1995)). Quick has decades of QMS experience, which shows that his testimony naturally flows from his own current and prior experience. *See id.* at 435 n.2 ("A trial judge's assessment of the prepared-solely-for-litigation factor is not, of course, a totally binary exercise. We recognize that many experts may look neither quite like the 'quintessential expert for hire' in this case nor quite like a pure research scientist/engineer whose loyalties are to the laboratory/field and not the courtroom.").

to establish that his opinion is reliable or why the other animal studies and the design files were unnecessary for Quick to review.

For these reasons, Quick's testimony is inadmissible, and Defendants' motion is granted.

B. Donna-Bea Tillman, Ph.D., MPA, FRAPS

Defendants offer Dr. Tillman as an expert witness to testify regarding "the FDA's medical device regulatory standards, the FDA's 510(k) clearance process, and postmarket safety." (ECF No. 134 at PageID #8654.) Plaintiff moves to exclude three opinions: (1) the meaning of the Marlex MSDS related to polypropylene used in the Ventralight ST devices, (2) opinions regarding the FDA's quality system regulations, and (3) any testimony relating to FDA websites that discuss hernia mesh. Dr. Tillman's MSDS and FDA website opinions are inadmissible, but her opinion regarding the FDA's quality system regulations is admissible. Thus, Plaintiff's motion is granted in part and denied in part.

1. MSDS meaning

Plaintiff contends that Dr. Tillman is unqualified to offer opinions about the meaning of MSDSs in the 510(k) process because she has no experience with the Occupational Safety and Health Administration ("OSHA"), the federal agency that requires the creation of MSDSs, and that her methods for reaching her MSDS opinions are unreliable. (ECF No. 113 at PageID #7690–91.) However, the Court need not address Dr. Tillman's qualifications or the reliability of her opinion because the Court ruled earlier that the Marlex MSDS was only admissible as evidence of Defendants' knowledge and inadmissible hearsay if offered to demonstrate that polypropylene was unsafe for permanent implantation in the human body. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6603657, at *4–5. Dr. Tillman's testimony as to the meaning of MSDSs, specifically that they are not indicative of safety for consumers or end users of polypropylene devices, is irrelevant to what

Defendants actually thought the MSDS meant or what they otherwise knew about the risks of the polypropylene at the time the Ventralight ST was designed and marketed. This opinion is therefore inadmissible.

2. FDA's quality system regulations

Next, Plaintiff asserts that Dr. Tillman's background discussion about the FDA's quality system regulations, particularly how it fits within the regulatory scheme, is unreliable because she does not intend to offer an opinion about Defendants' quality systems. (ECF No. 113 at PageID #7692.) Defendants agree that Dr. Tillman does not purport to offer an opinion and posit that this portion of her expert report is background helpful to the trier of fact. (ECF No. 134 at PageID #8659–60.) To the extent that Dr. Tillman provides this testimony as background and not a description of law, she may testify by way of her experience.

3. FDA's hernia mesh website

Plaintiff moves to exclude Dr. Tillman's opinions related to the FDA's hernia mesh specific website. (ECF No. 113 at PageID #7692.) Specifically, Plaintiff challenges Dr. Tillman's following opinion as unreliable because she lacks knowledge about the FDA's process with regard to the hernia mesh website:

> In my experience, if FDA had any questions or concerns about the safety or effectiveness of hernia mesh products current on the market, these concerns would have been expressed on this publicly available website page.

ECF No. 113-1 at PageID #7738.) Plaintiff contends that this opinion lacks "any foundation." (ECF No. 113 at PageID #7692.) The Court agrees. Even if Dr. Tillman had experience and knowledge related to the FDA's vetting process for websites, she lacks any knowledge about the FDA's vetting for this particular website because she did not participate in the vetting process.

Accordingly, her opinion is simply speculation. Dr. Tillman's opinion regarding the FDA website is inadmissible.

C. Kimberly A. Trautman, M.S.

Plaintiff moves to exclude the opinions and testimony of Kimberly A. Trautman, M.S. (ECF No. 72.) Most of Trautman's report is general, concluding that Defendants were compliant with FDA QMS regulations based on her review of records from 2004 to 2017, though she makes some specific references to certain FDA communications related to the Composix Kugel device. (ECF No. 72-1 at PageID #4539–42.) Before addressing any of the parties' arguments, the impact of prior motions in limine decisions on Trautman's opinions and testimony must be noted. Evidence of FDA inspections and third-party audit evidence about other devices demonstrating non-compliance with FDA regulations is inadmissible character evidence under Federal Rule of Evidence 404 if offered to prove the Ventralight ST's nonconformity with FDA regulations. *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 81821, at *6–7. Likewise, evidence related to FDA compliance, as opposed to noncompliance, with other devices if offered to show compliance with the Ventralight ST is also impermissible propensity evidence. As this Court has explained, "character or propensity evidence may be of bad *or* good character; Rule 404 makes no distinction. Therefore, Plaintiff would have no occasion to rebut evidence of Defendants' general good character because it would also be inadmissible propensity evidence." *Id.* at *5 (discussing evidence that Defendants have always manufactured devices in accordance with FDA guidelines and regulations). Thus, Defendants cannot offer Trautman's opinion or testimony regarding their compliance with FDA guidelines and regulations for devices other than the Ventralight ST. For the remainder of this analysis, the only opinions considered are those that can be construed as addressing Defendants' compliance in designing and manufacturing the Ventralight ST.

Plaintiff argues that Trautman's opinions and testimony should be excluded because she is unqualified to offer opinions about what the FDA believed or considered and because those opinions are unreliable. (ECF No. 72 at PageID #4518–21.) Plaintiff does not appear to contest that Trautman is qualified to offer opinions regarding whether Defendants were in fact in compliance with the FDA; instead, Plaintiff takes issue with Trautman's interpretation of certain actions or inactions of the FDA as indicating that the FDA believed they were in compliance. (*Id.* at PageID #4517–18.) Trautman is qualified to opine whether Defendants complied with FDA regulations, but she is not qualified to opine on the opinions and beliefs of the FDA. For this reason, there is no need to address whether her method for reaching her FDA-belief opinions are reliable.

Trautman is eminently qualified to opine on whether Defendants were in compliance with the FDA. She has over 30 years of experience in medical device quality systems and international regulatory compliance/affairs, including 20 years with the FDA. (ECF No. 72-1 at PageID #4555–58.) Trautman worked for the FDA in the Center for Devices and Radiological Health, the division responsible for ensuring the safety of medical devices used in the United States, from 1991 to 2016. (*Id.*) During her tenure, Trautman wrote the current QMS regulation. Currently, Ms. Trautman is the Executive Vice President Medical Device International Services for NSF Health Science, a division of NSF International. (*Id.* at PageID #5557.) Accordingly, Trautman may offer opinions such as that Defendants appeared to be in compliance with the QMS regulations during the design and manufacture of the Ventralight ST.[5]

However, Defendants fail to show that this translates the ability to opine on the beliefs of

[5] Evidence of compliance with FDA regulations is not the standard of care that the jury will consider. Although such compliance is evidence that the standard of care is met under Utah law. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6603657, at *10 (citing *Downing*, 194 P.3d at 948).

the FDA. For example, Trautman opines in one instance that Certificates of Foreign Governments ("CFGs") is "evidence that the FDA considered Davol to be in substantial compliance of the [QMS] regulation through the vast majority of the 14 years described above." (ECF No. 72-1 at PageID #4546.) Although Trautman may rely on her expertise to explain the meaning of receiving a CFG, such as that a CFG is not issued when a manufacturer is not in substantial compliance, she cannot opine as to what the FDA believed when it issued the CFG. Expert testimony "on the intent, motives or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise." *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004); *see also In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (granting motion to exclude an expert who was a former FDA employee "from testifying as to as to the knowledge, motivations, intent, state of mind, or purposes of Merck, its employees, the FDA, or FDA officials" because "her regulatory expertise does not give her the ability to read minds."); *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-CV-144, 2015 WL 13022172, at *9 (S.D. Ohio Oct. 2, 2015) (same).

An individual who was part of those decisions at the FDA might in some limited circumstances testify to the FDA's motivations. Trautman does not purport to be one of those individuals. Indeed, Trautman stated that she was not involved in any investigations or evaluation at the FDA related to Defendants. (ECF No. 111-1 at PageID #7500, p. 144.) Moreover, this testimony would not be expert testimony, *i.e.* technical or scientific. *See* Fed. R. Evid. 702. A jury is free to infer that the FDA harbored such beliefs based on the FDA's actions, with the assistance of Trautman's testimony, but Trautman herself may not make this inference. *In re E. I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 345 F. Supp. 3d 897, 914 (S.D. Ohio 2015).

Defendants offer no persuasive counterarguments. Defendants argue that Plaintiff "misses

the point" by pointing out that Trautman was uninvolved in the FDA decisions behind actions such as the CFG given her experience with the FDA's QMS regulations. (*Id.* at PageID #7468.) Defendants collapse the two types of opinions that Trautman gives: one as to whether Defendants were compliant with FDA regulations and one as to whether the FDA believed that Defendants were complaint. The first is amenable to expert evaluation, including the document review undertaken by Trautman. The second is a determination that only those involved in the FDA evaluation and decision-making process can know.

For these reasons, Plaintiff's motion is granted as to Trautman's non-Ventralight-ST compliance opinions and Trautman's testimony and opinion regarding the FDA's beliefs.

D. Marion J. Fedoruk, MD

Plaintiff challenges two opinions of Dr. Fedoruk's: "(1) the FDA's position on whether Material Safety Data Sheets (MSDS) are a comprehensive source of information upon which to make a chemical risk assessment or clinical decision; and (2) the motivation of medical use statements made in MSDS issued by certain companies." (ECF No. 43 at PageID #2422 (footnote omitted).) Additionally, oral argument was held on this motion. (ECF No. 298 at PageID #16566–79.) Both of these opinions are inadmissible.

Dr. Fedoruk's first opinion is inadmissible because it is irrelevant. The Marlex MSDS is admissible only to prove Defendants' knowledge of the risks presented by polypropylene. *In re Davol, Inc./C.R. Bard, Inc*, No. 2020 WL 6603657, at *4–5. Dr. Fedoruk's opinion about whether the FDA views the MSDS as evidence of safety is irrelevant to whether the MSDS put the Defendants on notice of the risks of polypropylene. *Supra*, Part III.B.1.

Even if this previous ruling were no bar, both of Dr. Fedoruk's opinions would

still be inadmissible. He cannot opine on the FDA's beliefs. *Supra* Part III.C. Nor may he opine on the reason the Medical Application Caution Statement was included in the MSDS. This is an issue of state of mind or intent of the manufacturer of the polypropylene MSDS, which is inappropriate for expert testimony. *Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *23 (S.D.W. Va. Feb. 7, 2015); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 574–75 (S.D.W. Va. 2014). To the extent that Dr. Fedoruk ruled out some bases for inclusion of the statement in the MSDS, he may not then draw the inference why the manufacturer included the statement—only a jury could. *In re E. I. du Pont de Nemours & Co.*, 345 F. Supp. 3d at 914.

Accordingly, Plaintiff's motion is granted.

E. Greg Richey, MS, CIH, CSP, FAIHA

Plaintiff challenges Richey's opinions "related to the content of certain MSDS documents prepared by the manufacturers of the raw polypropylene resin used in several hernia mesh devices" on the basis that he is unqualified to offer them and that his opinions are unreliable. (ECF No. 97 at PageID #6999.) Defendants explain that Richey provides context regarding OSHA and the Pro-fax 6523 MSDS. (ECF NO. 125 at PageID #8522.) These opinions are irrelevant as to whether Defendants knew of the risks of permanently implanting polypropylene—the only issue the MSDS is admissible to prove. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6603657, at *4–5. Therefore, Richey's opinions are inadmissible, *supra* Parts III.B.1, III.D, and Plaintiff's motion is granted.

F. Thomas Michael Galassi, MPH, CIH

Plaintiff challenges Galassi's opinions on "issues related to the content of certain MSDS documents prepared by the manufacturers of the raw polypropylene resin used in several hernia mesh devices." (ECF No. 138 at PageID #8899). The essence of Galassi's opinion is that the MSDS is required by OSHA regulations, which pertain to occupational safety, *i.e.* safety in the

workplace, not consumer or patient safety. (ECCF No. 154 at PageID #9427.) As with other regulatory experts, Galassi's MSDS opinions are inadmissible because they do not speak to what Defendants knew about the risks of polypropylene from the Marlex MSDS. *Supra* Parts III.B.1, III.D, III.E. Accordingly, Galassi's opinions related to MSDSs are irrelevant and inadmissible. Plaintiff's motion is granted.

IV. Conclusion

For these reasons, Defendants' motion to exclude Quick's opinions and testimony (ECF No. 32) is **GRANTED**, Plaintiff's motion to exclude Dr. Tillman's opinions and testimony (ECF No. 113) is **GRANTED IN PART and DENIED IN PART**, Plaintiff's motion to exclude Trautman's opinions and testimony (ECF No. 72) is **GRANTED IN PART and DENIED IN PART**, Plaintiff's motion to exclude Dr. Fedoruk's opinions and testimony (ECF No. 43) is **GRANTED**, Plaintiff's motion to exclude Richey's opinions and testimony (ECF No. 97) is **GRANTED**, and Plaintiff's motion to exclude Galassi's opinions and testimony (ECF No. 138) is **GRANTED**.

IT IS SO ORDERED.

6/28/2021
DATE

s/ Edmund A Sargus, JR.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE